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**CANCER ACTION NY**
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Cancer Prevention By Pollution Minimization

12/30/03

Food and Drug Administration
Dockets Management Division
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Dear Commissioner of the US Food and Drug Administration,

This petition is presented to the US Food and Drug Administration (US FDA) for the purpose of requesting the issuance of three rules that would serve to further protect the American public from exposure to certain persistent organochloride pollutants (POPs), including: chlorinated dibenzo-p-dioxins (CDDs), chlorodibenzofurans (CDFs), and dioxin-like PCBs. Petitioning is herein exercised pursuant to 21 CFR Part 10.30. These pollutants bioaccumulate in animal fat, and thus contaminate animal fat foods. Health damages associated with CDD and CDF exposure are carefully set forth in the US Environmental Protection Agency's (US EPA) draft dioxin reassessment. The damaging effects of exposure to these chemical compounds are causally related to: cancer, behavioral and cognitive disorders, endocrine disruption, cardiovascular disease, immune system dysfunction, and type II diabetes. The Institute of Medicine of the National Academies recently published "Dioxins and Dioxin-like Compounds in the Food Supply: Strategies to Decrease Exposure". A key recommendation of this report is that girls and women of childbearing age reduce their consumption of animal fat foods due to the presence of the dioxin and dioxin-like contaminants.

Will the US FDA issue a rule establishing a uniform CDD, CDF and dioxin-like PCB testing program for regional milk production areas of the United States? Milk consumption tends to occur within a regional area of production. Exposure differences will mirror the differences in levels of regional contamination. A regional testing program would detect differences between the levels of contamination that exist in the various milk production areas. This information could be used to focus the efforts of government and non-government organizations to minimize CDD, CDF and dioxin-like PCB releases to the environment on those areas of greatest milk fat contamination.

Will the US FDA issue a second rule requiring that foods containing animal fat be labeled such that consumers are made aware of the presence of CDD, CDF and dioxin-like PCB contaminants, and further apprised of the fact that these chemical compounds are anthropogenic pollutants, designated as known to cause cancer in humans? The need for this rule arises from the excess cancer risk associated with consumption of animal fat foods contaminated with dioxins and dioxin-like compounds. The US EPA has upgraded the cancer risk of dioxin and dioxin-like compound exposure substantially. In June of 2000, a further section of the Agency's dioxin reassessment, "Part III: Integrated Summary and Risk Characterization for 2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD) and Related Compounds", was published, setting forth the research basis for this change. Epidemiologic studies of several exposed groups: workers who manufactured or applied dioxin contaminated pesticides, including pentachlorophenol, and 2,4,5-T; victims of an industrial accident in Seveso, Italy, which released kilogram quantities of dioxin; and US Air Force personnel engaged in Project Ranch Hand, the spraying of Agent Orange during the Vietnam War, demonstrate a linear relationship between dioxin exposure and increased cancer risk. According to US EPA, the average American consumes a quantity of animal fat sufficient to impose a dioxin and dioxin-like compound exposure of 1 pg dioxin TEQ/kg bw/day. This level of exposure is associated with a 1 in 1000 excess risk of developing cancer. Doubling one's intake of animal fat food results in a doubled cancer risk. During the 1970s and 1980s, dioxin and dioxin-like compound levels in animal fat foods were considerably higher than current levels. Those who consumed animal fat produced over that time period have a significantly higher lifetime cancer risk. Labeling would be especially valuable to the moderate to heavy consumer of animal fat foods who consumed these foods through the 1970s and 1980s, and who continues to consume them. Such an individual would be placed at an excess cancer risk of at least 1 in 100 based upon lifetime intake and body burden.

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Will the US FDA issue a third rule banning the feeding of animal fat to food animals? This ban would be highly effective in bringing about a decrease in the levels of POPs contaminating animal fat. It was recommended by the panel of experts who authored the Institute of Medicine report referred to above that efforts be made to stop the recycling of animal fat in animal food production.

Please utilize the following documents in making a determination as to whether or not to issue the requested rules: US EPA, "Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds", 2000; Institute of Medicine of the National Academies, "Dioxins and Dioxin-like Compounds in the Food Supply: Strategies to Decrease Exposure", July 2003; National Toxicology Program, "The Tenth Biennial Report on Carcinogens"; US Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, "Toxicological Profile for Chlorinated Dibenzo-p-Dioxins (Update), December 1998; US Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, "Toxicological Profile for Chlorodibenzofurans, May 1994; and US Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, "Toxicological Profile for Polychlorinated Biphenyls", November 2000.

Providing the US FDA with information, which would serve to argue against the issuance of these rules, is a straightforward matter. Dairy and meat industry profits could be affected negatively.

In so far as the first requested rule is concerned, the short-term losses of the dairy industry would be made up for by the long term gains that would accrue from eventual quality improvements resulting from focused efforts to reduce POPs releases in the regions of highest contamination. Open waste burning elimination is the type of endeavor that could produce such an improvement in the quality of dairy products.

Regarding the adverse impacts of the second requested rule upon the profitability of the dairy and meat industries, it is likely that consumers would choose to purchase lower quantities of food containing animal fats when informed of the disease risk associated with dioxin and dioxin-like compound exposure by way of product labeling. These potential losses are far outweighed by the benefits of chronic disease prevention resultant from informed dietary choices.

The rule banning the use of animal fat in the feeds of food production animals could reduce the profits of the rendering industry. This loss would be offset by the improvements in public health that result from decreased POPs exposure.

No negative impacts upon the environment are anticipated for the implementation of the first and second proposed rules. Depending upon what uses are made of animal fat not fed to animals, negative impacts upon the environment could result from implementation of the third proposed rule. If animal fat were to be used as a fertilizer, soil levels of POPs would be increased.

To the best of my knowledge this petition includes all information relevant to the matters of dioxin and dioxin-like contaminants of animal fat and the negative impacts upon the public health caused by exposure to these contaminants. Information both favorable and unfavorable to the petition is included.

Respectfully submitted by,

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